Cardinal Health
7000 Cardinal Place
Dublin, OH 43017

cardinalhealth.com

CardinalHealth

March 19, 2012

Dear Valued Customer:

As you are aware, prescription drug abuse has reached epidemic proportions in our country. Under the Drug Enforcement Administration's (DEA) regulations, all participants in the pharmaceutical supply chain have a responsibility to help prevent diversion and prescription drug abuse. As a distributor, we are required, among other things, to operate a system that detects suspicious orders of controlled substances, report them to the agency, and, where further inquiry doesn't satisfactorily explain the order, not fill those orders.

We take this responsibility seriously and have invested heavily to develop a best practice anti-diversion program utilizing all information we have access to as a distributor. Our controls feature a system of advanced analytics and teams of anti-diversion specialists and investigators to identify red flags that could signal diversion. When the program raises a red flag, our anti-diversion specialists investigate further and must use their professional judgment to determine the appropriate action.

Satisfying our anti-diversion responsibilities is not a precise science and requires human judgment. The DEA regulations broadly define suspicious orders to include those of unusual size, those that deviate from a normal pattern, and those of unusual frequency. That said, we recognize that the needs of pharmacies are varied, and factors such as pharmacy size, hours of operation, patient demographics, and proximity to hospitals, nursing homes, cancer clinics and hospice providers are factors to consider. Moreover, as the enforcement environment has evolved, we find we are required to make judgments involving the actions and intent of licensed doctors and pharmacists.

As a pharmacy and participant in the pharmaceutical supply chain, you have your own set of obligations under the DEA regulations. As part of our effort to work collaboratively with you as a customer to prevent prescription drug diversion, I am enclosing a case study we have created to help you understand your "corresponding responsibility" under the Federal Controlled Substances Act to fill legitimate prescriptions written for legitimate purposes. We understand the challenges and complexities of meeting the demands of the ever evolving problem of substance abuse and hope you find this booklet helpful in your practice.

We know that the vast majority of our customers are healthcare professionals of the highest integrity dedicated to providing the best possible care to their patients and we are dedicated to doing all we can to support you in that endeavor. We trust that you know we want to make a real difference – in your business, in your community and in the effort against prescription drug abuse.

Please contact Michael Moné at 614.757.5104 if we can be of assistance to you as we work together to ensure the availability of these critical medications to meet legitimate medical need while preventing their diversion to illegitimate channels.

Sincerely,

Jon Giacomin
President, U.S. Pharmaceutical Distribution

DEFENDANT EXHIBIT
CAH-WV-00458

Supply Chain Integrity

CardinalHealth
Essential to care™

# Is it legitimate? Understanding the Pharmacist's Corresponding Responsibility

Pharmacists are an invaluable part of the healthcare team dedicated to serving the needs of patients. One aspect of patient care that pharmacists can have a significant impact on is the proper therapeutic management of chronic pain patients. Chronic pain patients, in particular, create a unique set of challenges, but also an opportunity for pharmacist interventions.

Pain is a serious medical condition that can significantly decrease the quality of life of patients, yet all too often goes undertreated. However, the medications used to treat pain in patients can often have the potential for addiction as well as posing a significant abuse potential. Now, more than ever, regulators expect pharmacists to take responsibility for ensuring that controlled substances are being dispensed to patients for a legitimate medical purpose and not being abused or diverted.

The "diversion" of controlled substances refers to any process by which a controlled substance leaves the legitimate system of distribution, and enters an illegal channel. While diversion can exist in many forms, some of the most common methods of diversion are via theft and burglary. However, diversion also exists when controlled substances are acquired by a person for anything other than a legitimate medical purpose. Methods of this can include: doctor shopping, patients presenting to unknowing physicians with deliberately false medical symptoms, or even the occasional physician who knowingly writes a prescription for a patient without a legitimate medical purpose.

Regulators have increasingly scrutinized whether pharmacists are identifying prescriptions that are written without a legitimate medical purpose. The Drug Enforcement Administration (DEA) has interpreted the Federal Controlled Substances Act to impose on pharmacists a "corresponding responsibility" along with physicians to ensure that controlled substance medications are only dispensed to patients based on prescriptions written for a legitimate medical purpose and in the normal course of professional practice. Unfortunately, pharmacists must often meet this corresponding duty with only limited or imperfect information.

While state laws vary, DEA requires the following information on all controlled substance prescriptions: the full name and address of the patient, the full name, address, and DEA number of the prescriber, the drug name, strength, dosage form, quantity, directions for use, and any refills if applicable. Yet, even with each of these elements present, DEA has explained that the prescription is not necessarily "valid." This is because, as alluded to previously, the prescription may have been written without a legitimate medical purpose.

## How then are pharmacists to meet this corresponding duty pertaining to prescription validity?

While DEA has provided no "bright line" rule that can be applied to determine whether a prescription has been issued for a legitimate medical purpose, it has explained that problem prescriptions can often be more readily identified by using common sense, practicing "good pharmacy," and looking for "red flags" that suggest the prescription may not be legitimate. State and Federal legal cases can provide some insight on what a pharmacist's obligations are in meeting this responsibility, yet the key, according to those cases, is to use professional discretion.

Every state pharmacy practice act requires that pharmacists perform some version of drug utilization review (DUR) prior to filling a prescription. When performing DUR, pharmacists should look for "red flags" that suggest that the prescription may not be legitimate. In *United States v. Rosen*, the DEA cited several "red flags" in finding that the prescriptions were not written for legitimate medical purposes. These included:

- The practitioner issued an inordinately large quantity of prescriptions.
- The prescribers warned and instructed the patient on how to use different pharmacies to avoid detection or suspicion in prescription monitoring programs.
- The prescriber issued the prescriptions knowing the patient was not going to personally use them, but the drugs would be delivered to another person.
- There was no logical relationship between the drugs prescribed and the treatment for the conditions documented in the patient's chart.
- The practitioner prescribed drugs at intervals that were inconsistent with legitimate medical treatment.
- Instead of professional medical terminology, the prescriber used or documented street slang for drugs and paraphernalia.
- The practitioner issued multiple prescriptions in a manner to spread them out and hide the activity.

While it is difficult for a pharmacist to identify all of these "red flags," it is clear that DEA expects pharmacists to be diligent in meeting their corresponding responsibility, and to be on the alert for these types of issues. In particular, DEA has explained how communication both with the prescriber and the patient can be valuable in helping to identify these types of "red flags."

**In a recent case brought by DEA against East Main Street Pharmacy, located in Ohio, because the following red flags were ignored DEA revoked the pharmacy's DEA registration:[2]**

- The prescribing of drug "cocktails," consisting of prescriptions for oxycodone, hydrocodone, alprazolam, and carisoprodol; a combination well-known in the pharmacy profession as being used by patients abusing prescription drugs.
- No individualization of dosing by the prescribing physician.
- Filling multiple prescriptions for the strongest dosages of hydrocodone and alprazolam.
- Requests for early dispensing of refills.
- Refills of prescriptions of patients or doctors located hundreds of miles away from the pharmacy.

Other facts that supported revocation, according to DEA, included: an overwhelming proportion (95 percent) of prescriptions filled by the pharmacy were controlled substance prescriptions; the pharmacist did not reach out to or otherwise contact other pharmacists to determine why they were not filling a particular doctor's prescriptions; the pharmacy filled prescriptions of patients that travelled to the pharmacist in groups; and the pharmacy filled a high percentage of controlled substance prescriptions for cash paying customers. The decision noted that "[a]ny reasonable pharmacist knows that a patient that wants to pay cash for a large quantity of controlled substances is immediately suspect." With evidence that the pharmacy's customers often complained of having to pay extra for lab tests and that many other pharmacists refused prescriptions from the prescriber in question, DEA explained that the fact that the pharmacist verified the prescriptions as "legitimate" based on the fact that the prescribing practitioner performed MRIs and blood tests on the patients did not mean the pharmacist had fulfilled his obligations under the corresponding responsibility doctrine.

The East Main Street case represents particularly egregious conduct, but the message sent by the decision is clear: pharmacists, who repeatedly ignore red flags and fill prescriptions that are not issued for a legitimate medical purpose, can and will be prosecuted, face administrative action, or both. In recent years, DEA has increased the number of administrative actions against pharmacies, in its approach to ensuring that pharmacists are fulfilling their corresponding responsibility. Possible sanctions include suspension or revocation of the pharmacy's DEA registration, as well as the seizure of the pharmacy's and owner's assets of a pharmacy under federal drug trafficking laws, the imposition of civil penalties up to $10,000 per violation, and criminal prosecution, meaning that the pharmacy owner and the pharmacists who are dispensing can be sent to prison. Although violations of the controlled substance laws and regulations can lead to both administrative and criminal action, criminal prosecution is typically reserved for intentional and knowing conduct, where the pharmacy's intent to violate the law is clear.

Note that the presence of one or more of the red flags does not necessarily indicate that the prescription is not legitimate and should not be dispensed, but DEA does expect that in light of those red flags the pharmacist will exercise additional diligence before filling the prescription. Among other things, the prescriber should be contacted to determine the diagnosis that supports the prescription. A doctor that is truly providing pain management will gladly provide the pharmacist – a fellow health care practitioner – diagnosis information needed to support the medical necessity for the prescription. A refusal to cooperate by the prescriber is a red flag that may indicate the prescriber is not acting in good faith and the prescription is not legitimate.

Similarly, DEA has explained that educating yourself about the doctor's practice is important. Additional questions that the DEA has considered in recent enforcement actions can be used as a guide for pharmacists. Such questions include:

- Is the physician located in the same geographical area as the pharmacy?
- Does the specialty of the prescriber fit the prescribed medication and the diagnosis?
- What does the prescriber's office look like? Are there patients waiting in line outside the prescriber's office?
- How long has the prescriber been in practice in that office or area?
- Does the physician cater to primarily a younger patient population, between 20 and 40 years of age?
- Do the majority of the patients of the prescriber receive the same medication(s) in the same quantity, indicating a lack of individualized treatment?
- Does the prescriber see an unusually large number of patients per day?
- Is the patient paying cash? If so, this is especially a red flag for oxycodone, hydrocodone, alprazolam and carisoprodol.
- Is the patient requesting early refills or coming in for frequent fillings?
- Do patients with controlled substance prescriptions arrive in the pharmacy in groups?
- Are the patients asking for a specific generic manufacturer or by color or street slang name?
- Do patients appear to be exchanging or selling those controlled substance prescriptions in or nearby the pharmacy (e.g., in the parking lot)?

As pointed out in the East Main decision, simply obtaining diagnosis information may not be enough. Doctors who provide the same or similar diagnosis for a large number of patients may not be acting in good faith. DEA may require further diligence, including accessing a state prescription drug monitoring database , if one is available in your state, to see whether the doctor has a pattern of prescribing controlled substances to a large number of patients, or whether the patients are engaged in "doctor shopping," and accessing controlled substances from multiple prescribers. The verification that the physician's DEA registration and state license are valid and in good standing, by accessing the DEA registration database on the web and the state physician licensure database, is also important. If a physician has disciplinary history related to the prescribing of controlled substances, caution should be exercised even if the prescriber has an active medical license and DEA registration.

Counseling the patient and assessing whether the patient is benefitting from the prescribed therapy is also an important tool. DEA has also explained how communicating with other pharmacies in the area, both directly and through trade organizations, can be helpful to see whether they have had concerns with a particular physician or patient.

Further guidance can be found from DEA in The Pharmacist's Guide to Prescription Fraud available at http://www.deadiversion.usdoj.gov/pubs/brochures/pharmguide.htm[4]

This publication provides tips to help identify fraudulent prescriptions and purported prescriptions that are not issued for a legitimate medical purpose. As stated in the DEA guidance:

> *Loose or routine dispensing procedures without controls and professional cautions, are invitations to the drug abuser. Proper controls against fraudulent prescriptions can best be accomplished by following common sense, sound professional practice, and using proper dispensing procedures and controls.*
>
> *Have your pharmacy staff help protect your practice from becoming a source for prescription drug diversion. Become familiar with which drugs are popular for abuse and resale on the streets in your area. Drug abuse prevention must be an ongoing staff activity.*

Simply put, exercising diligence, and using good professional judgment, will go a long way towards ensuring that you are fulfilling your responsibilities under state and federal law.



1 *United States v. Rosen*, 582 F2d 1032 (5th Cir. 1978)

2 East Main Street Pharmacy, 75 Fed. Reg. 66149 (Oct. 27, 2010)

3 According to the National Association of Boards of Pharmacy (NABP) 2012 Survey of Pharmacy Law at page 69, all but six states and Puerto Rico lack some type of controlled substance prescription monitoring program.

4 The Pharmacist's Guide to Prescription Fraud available at http://www.deadiversion.usdoj.gov/pubs/brochures/pharmguide.htm

About the Authors

## Edward D. Rickert, B.S. Pharm., J.D.,

is a partner at Krieg DeVault, LLP, where he is a member of the firm's Health Care and Life Sciences Practice Groups. He is also an adjunct professor at the University of Illinois College of Pharmacy, where he teaches the pharmacy law course. Ed's law practice is focused in the representation of pharmacies and pharmacists, as well as drug manufacturers and drug wholesalers, in civil and regulatory matters. He has represented pharmacies and pharmacists in matters before state boards of pharmacy across the country, and has defended pharmacies, pharmacists and other providers in civil, criminal and administrative matters brought by the Drug Enforcement Administration in cases alleging violations of the federal Controlled Substances Act, including diversion, and before the Food and Drug Administration and state Departments of Health in manufacturing/compounding cases.

Ed is active in many state and national pharmacy organizations, and is a past president of the American Society of Pharmacy Law. He is currently the Director of Government Affairs for the Illinois Council of Health Systems Pharmacists. He is a frequent speaker at local, state and national meetings on a variety of topics related to legal and regulatory issues in pharmacy.

Ed can be reached by email at erickert@kdlegal.com, or by phone at 312.423.9308.

## Eli G. Phillips, Jr., Pharm.D., J.D.,

is currently an Assistant Professor of Pharmacy Practice and Special Counsel to the Dean at the University of the Incarnate Word, Feik School of Pharmacy in San Antonio, Texas. He is also the Managing Member of Healthcare Advising, LLC a private consulting firm, and Adjunct Professor of Law at St. Mary's University School of Law in San Antonio.

Prior to his current roles, Dr. Phillips received his Pharmacy Degree from Wilkes University located in Wilkes-Barre, Pa. followed by his Law Degree from Drexel University located in Philadelphia, Pa. He has worked as a full-time pharmacist for CVS Pharmacy, and completed law internships with the Drug Enforcement Administration, Office of Chief Counsel in Arlington, VA and the Governor's Office of General Counsel for the Commonwealth of Pennsylvania, Department of Corrections, in Harrisburg, Pa.

His current interests include research and consulting on licensing and regulation of professionals and cases involving drugs of addiction, including prescription diversion. He can be contacted at eliphillipsjr@lawpharm.com, or 210.883.1071.

CardinalHealth
Essential to care™

cardinalhealth.com